

REMARKS

The Rejection

The sole basis for rejection of claim 61, the only claim considered, is based on asserted anticipation by documents by Kleinerman, *et al.*, which describe utilization of MTP-PE encapsulated in liposomes as an anti-tumor treatment. The Office argues that this treatment would inherently anticipate the claims.

Attention is drawn to the wording of claim 61. The claim is directed to method to *ameliorate* mucositis in a subject. This wording assumes that the subject is exhibiting mucositis at the time of treatment - otherwise the mucositis could not be ameliorated. There is nothing in the cited documents which suggests that the subjects exhibit mucositis. Indeed, this is a classic case of a new medical use. A different patient population is targeted from the patient population set forth in the two cited documents by Kleinerman, *et al.* The population of the claims is the population that exhibits mucositis, not that which exhibits malignancies. This is typical of claims where a new use for an old composition is found. Surely, the Office is aware of the many patents that have issued directed to new disease indications for old drugs. This is exactly the case here.

It should be clear from the Restriction Requirement that the Office recognizes that this is a valid distinction in the present case. The Office took the position that ameliorating myelosuppression, ameliorating mucositis, and ameliorating peripheral neuropathy in a subject being treated with a neoplastic agent were all separate inventions and were also separate inventions from methods to treat neoplasia. If these are separate inventions, how can a document which describes a treatment of neoplasia inherently anticipate the separate invention of treating mucositis?

This is in contrast to the situation in the case cited in the Office action, *i.e.*, *Ex Parte Novitski*, 26 USPQ2d 1389 (BPAI 1993), where the claims were directed to inoculating a plant against nematode infection. There was no requirement in these claims that the plant actually be infected by nematodes as there is a requirement here that the subject have mucositis. Therefore, the rejection applied by the Board in *Novitski* is inapposite in the present case.

Claim 56

It is recognized that claim 61 covers both the situation where treatment with the anti-neoplasia agent has been terminated and where it is still ongoing. Therefore, it is unclear, still, to applicants why claim 56 represents distinct subject matter. The Office states that the methods of these claims have different objectives, method steps, response variables and criteria for success. What differences would there be? In both cases the objective is to ameliorate the mucositis exhibited by the subject; in both cases the method step is to administer a pharmaceutical composition comprising MTP-PE encapsulated in multilamellar liposomes; the criterion for success in both cases is the amelioration of mucositis. It is not clear to applicants to what "response variables" the Office refers. Accordingly, it is believed that claim 56 is directed to the same subject matter as claim 61 and is slightly narrower in scope. It is clearly not a different invention.

CONCLUSION

In view of the forgoing, applicants request that both claims 56 and 61 be passed to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket No. 204372000901.

Respectfully submitted,

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By: Kate H. Murashige
Kate H. Murashige
Registration No. 29,959

Morrison & Foerster LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-5112
Facsimile: (858) 720-5125